

what is the RETAIN trial?

The **RETAIN** Study is a clinical research study sponsored by the National Institute of Allergy and Infectious Diseases (a part of NIH) and is conducted by the Immune Tolerance Network, a non-profit research consortium. The **RETAIN** study is evaluating a drug called alpha-1 antitrypsin (AAT).

AAT is an anti-inflammatory drug that affects immune cells that are thought to be involved in the development of type 1 diabetes. In mice, AAT can halt the destruction of beta cells, so doctors want to know if it will do the same in people, in a safe manner.

It is important to know that AAT is not a new drug – another name for AAT is “Aralast NP.” Aralast and drugs like it have been safely used for over 20 years to treat some types of emphysema. However, because it has not been used before in people with type 1 diabetes, it is considered an experimental treatment.



PARTICIPATING IN CLINICAL TRIALS

A clinical trial is a research study that involves people who volunteer to take part in a study. It provides a way to learn about the effects of new medicines and/or about new uses for medicines. People choose to participate in clinical trials for many reasons. For some it is a chance to gain access to experimental therapies. For others it is an opportunity to advance medical research. But it is important to remember that participation in a clinical trial is completely voluntary.

WHAT NEXT?

You have been given this brochure because your doctor believes that participating in the **RETAIN** trial is an option you may want to consider. But choosing to participate in a clinical trial is a very personal decision. We encourage you to learn all you can about the study – our study doctors and staff will be happy to answer any questions you might have. Speak with family, friends and your family doctor, to help you reach a decision that is right for you. If you have more questions or would like to find out if you (or your child) are eligible for this study please visit our website at www.retainstudy.org.

RETAIN is being conducted by the Immune Tolerance Network and sponsored by the National Institute of Allergy and Infectious Diseases (NIH funded), with support from the Juvenile Diabetes Research Foundation. Aralast NP is a registered trademark of Baxter Inc.

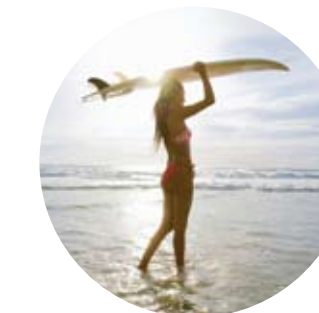
FOR MORE INFORMATION:



recently diagnosed
with type 1 diabetes?



we'd like to help.



retain
A RESEARCH TRIAL FOR NEW-ONSET TYPE 1 DIABETES

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RETAIN: a research trial of Aralast in new-onset type 1 diabetes

A WINDOW OF OPPORTUNITY

Type 1 diabetes is a chronic disease that develops when the immune system mistakenly attacks its own cells in the pancreas (called beta cells). Beta cells normally produce insulin, which allows the body to use energy from food and helps control blood sugar levels. Without insulin, the body cannot function properly.

By the time someone shows the physical signs of diabetes, the disease has already been at work for some time. So when a person is diagnosed with type 1 diabetes, a large portion of their beta cells have already been destroyed. The beta cells that remain, however, can still produce some of the body's much needed insulin.

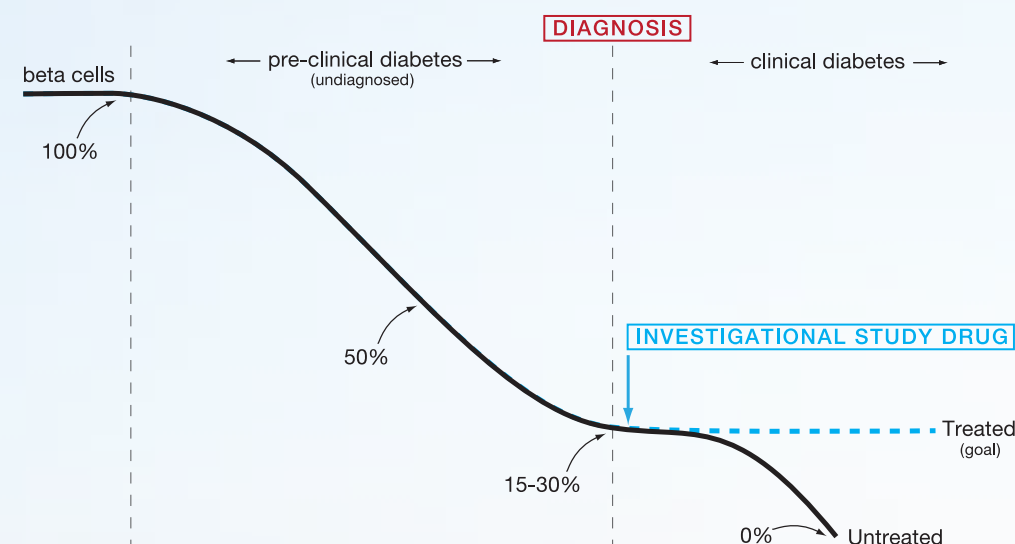
Researchers have found that even a small amount of insulin produced by a relatively small number of beta cells can be of great benefit to people with type 1 diabetes. It may help reduce the need for injected insulin and help maintain good control of blood

glucose levels. In turn, this can help prevent secondary complications of diabetes down the road.

For this reason, scientists are working hard to develop new treatments that can be given soon after diagnosis to preserve the remaining beta cells. This is the goal of the **RETAIN** clinical trial for newly diagnosed type 1 diabetes patients.

At the time of diagnosis, up to 15-30% of a person's beta cells may still be producing insulin.

Preserving even this relatively small number of cells can help diabetes patients lead healthier lives. Doctors are trying to find treatments that can be used soon after diagnosis to prevent any further loss of beta cells.



WHO CAN PARTICIPATE?

You may be eligible to participate if you:

- are between the ages of 8-35
- have been diagnosed with type 1 diabetes within the past 3 months

If you believe you (or your child) may qualify and would consider participating, the first step is to contact the nearest **RETAIN** clinical site. Our **RETAIN** doctors and nurses will explain the study to you in more detail. If you are interested, you will first be asked to attend a screening appointment to confirm whether you are eligible to participate. At this appointment, doctors will ask to review your medical history, and perform a physical exam and blood tests.

WHAT DOES PARTICIPATING INVOLVE?

A few things you should know about the **RETAIN** trial:

- participation will last up to two years (12 infusion visits and about 8 follow-up visits).
- participants will receive intravenous infusions of either the study drug or an inactive placebo a total of 12 times.
- all study-related care and study drug are provided at no cost to you.
- all participants will take part in an Intensive Diabetes Management program that aims to help patients gain better control of their disease and includes regular appointments with our expert diabetes care team.
- like any medication, AAT may have unwanted side effects and there is also no guarantee that AAT will work or that you will receive the active drug (rather than the placebo).
- you may or may not get better in this study but doctors can use what they learn to help people with diabetes in the future.

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